UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, et al. Plaintiffs, v. HANMI USA, INC., et al. Defendants.	Civil Action No. 11-760 (JAP) **OPINION**

PISANO, District Judge.

This is a Hatch-Waxman patent infringement action brought by Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc. and KBI-E Inc. (collectively, "AstraZeneca" or "Plaintiffs") against defendants Hanmi, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd. and Hanmi Holdings Co., Ltd. (collectively, "Hanmi" or "Defendants"). Presently before the Court are five motions by Hanmi seeking summary judgment. The Court heard oral argument on three of the motions on June 20, 2012, and decides the remaining motions without oral argument pursuant to Federal Rule of Civil Procedure 78. This Opinion addresses two of the five pending motions – those motions designated by the parties as Motion No. 1 and Motion No. 5. The remaining motions shall be addressed in a separate Opinion. For the reasons below, the Court denies Hanmi's Motions No. 1 and No. 5.

I. BACKGROUND

AstraZeneca is the holder of approved NDA No. 21-553 permitting the marketing and sale of AstraZeneca's esomeprazole magnesium product known as Nexium. Esomeprazole is the (–) or S enantiomer of omeprazole, which is a drug known as a proton pump inhibitor. Nexium is used for the treatment of four indications: treatment of gastroesophageal reflux disease (GERD); risk reduction of NSAID associated gastric ulcer; H. pylori eradication to reduce the risk of duodenal ulcer recurrence; and pathological hypersecretory conditions including Zollinger-Ellison syndrome. Hanmi has submitted New Drug Application No. 202342 to the United States Food and Drug Administration ("FDA") seeking approval to market esomeprazole strontium capsules in the United States to treat these same indications. Hanmi provided notice to Plaintiffs in December 2010 that it intends to market its esomeprazole strontium products before the expiration United States Patent No. 5,714,504 ("the '504 patent") and United States Patent No. 5,877,192 ("the '192 patent"), which are owned by Plaintiff AstraZeneca AB and listed in the FDA's Orange Book as covering the Nexium product and its uses. This lawsuit followed. The patents-in-suit cover pharmaceutical compositions containing alkaline salts of esomeprazole and methods of use thereof.

II. SUMMARY JUDGMENT MOTIONS

A. Legal Standard

1. Summary Judgment

A court shall grant summary judgment under Rule 56 of the Federal Rules of Civil Procedure "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The substantive law identifies which facts are critical or "material." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242,

248 (1986). A material fact raises a "genuine" issue "if the evidence is such that a reasonable jury could return a verdict" for the non-moving party. *Healy v. N.Y. Life Ins. Co.*, 860 F.2d 1209, 1219 n.3 (3d Cir. 1988).

On a summary judgment motion, the moving party must show, first, that no genuine issue of material fact exists. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party makes this showing, the burden shifts to the non-moving party to present evidence that a genuine fact issue compels a trial. *Id.* at 324. The non-moving party must then offer admissible evidence that establishes a genuine issue of material fact, *id.*, not just "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986).

The Court must consider all facts and their logical inferences in the light most favorable to the non-moving party. *Pollock v. American Tel. & Tel. Long Lines*, 794 F.2d 860, 864 (3d Cir. 1986). The Court shall not "weigh the evidence and determine the truth of the matter," but need determine only whether a genuine issue necessitates a trial. *Anderson*, 477 U.S. at 249. If the non-moving party fails to demonstrate proof beyond a "mere scintilla" of evidence that a genuine issue of material fact exists, then the Court must grant summary judgment. *Big Apple BMW v. BMW of North America*, 974 F.2d 1358, 1363 (3d Cir. 1992).

B. Motion No. 1 - Non-Infringement Of U.S. Patent No. 5,877,192

In its first motion, Hanmi seeks judgment of non-infringement of claims 1-11, 13-18 and 20-23 of the '192 patent. A patent infringement analysis proceeds in two steps—the first is proper construction of the relevant claims, and the second is a comparison of those claims to the accused product or method. *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed. Cir. 2009). To prove infringement, the patentee must show that an accused product or method is within the claim limitations of the patent-in-suit either literally or under the doctrine of equivalents. *See*

Amgen Inc. v. F. Hoffman-LA Roche Ltd, 580 F.3d 1340, 1374; *Warner Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997). "A patent is infringed if any claim is infringed ... for each claim is a separate statement of the patented invention." *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1220 (Fed.Cir.1995).

The '192 patent describes and claims a method for treating gastric acid related diseases with esomeprazole, and a method for the production of an esomeprazole-containing medicament for treating gastric acid related diseases. The claimed inventions are based on the discovery that esomeprazole has certain improved properties, and provides certain biological benefits, as compared to the prior art racematic compound omeprazole. For example, the inventors discovered that, compared to omeprazole, esomeprazole decreases the variation between individuals in plasma levels.

Those improved biological properties of esomeprazole versus omeprazole are reflected in the claims of the '192 patent. All of the claims at issue reflect at least one advantageous biological result as compared to omeprazole. By way of example, claim 1 of the '192 patent reads as follows:

> A method for treatment of gastric acid related diseases by inhibition of gastric acid secretion comprising administering to a mammal in need of treatment a therapeutically effective amount of a proton pump inhibitor consisting essentially of [esomeprazole] or a pharmaceutically acceptable salt thereof, *so as to effect decreased interindividual variation in plasma levels (AUC) during treatment of gastric acid related diseases*.

'192 patent, claim 1. (emphasis added). Other '192 patent claims similarly recite other improved properties of esomeprazole over omeprazole: "an increased average plasma level (AUC)" (claims 2 and 14), "less pronounced increase in gastrin levels in slow metabolisers during treatment of gastric acid related diseases" (claims 3 and 15), "a decreased CYP1A induction in slow metabolisers during treatment of gastric acid related diseases" (claims 4 and 16), "an

improved antisecretory effect during the treatment of gastric acid related diseases" (claims 5 and 17), and "an improved clinical effect comprising accelerated rate of healing and accelerated rate of symptom relief during the treatment of gastric related diseases" (claims 6 and 18).

In an earlier related case involving the '192 patent, this Court construed the biological property language in the claims of the '192 patent. *See AstraZeneca AB v. Dr. Reddy's Labs*., Ltd., 2010 WL 1981790 (D.N.J.) (the "DRL case"). The parties here have agreed to adopt the Court's prior constructions of the relevant claim terms for the purposes of this case. Hanmi 56.1 Satement ¶ 49; Astra Response. In the DRL case, the Court, citing *Griffin v. Bertina*, 285 F.3d 1029, 1033–34 (Fed. Cir. 2002), concluded that construction of the biological property claim terms was appropriate because these claim terms "express the invention of the claimed [esomeprazole] compound" versus omeprazole. *Dr. Reddy's*, 2010 WL 1981790 *11.

The basis of Hanmi's present motion is its assertion that each biological property claim term is a limitation requiring the active determination of the claimed comparative effect. Said another way, Hanmi argues that this Court has construed the relevant claims as requiring a comparative or "clinical" evaluation of the biological effects attained by one compound against another in order to practice the claimed invention. Hanmi states that when its product is sold in a pharmacy, there is no evidence that anyone will perform the comparative analysis Hanmi alleges is required by the claims at issue. As such, Hanmi contends AstraZeneca cannot prove direct infringement. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir. 2007) ("Direct infringement requires a party to perform each and every step or element of a claimed method or product.")

The Court finds Hanmi's arguments to be without merit. Hanmi's position that the claims at issue require performance of a clinical evaluation or comparative analysis between

esomeprazole (or one of its salts) and omeprazole in order to practice the invention is not supported by the Court's claim construction and is contrary the ordinary meaning of the claims. The biological language referred to above is not a claim limitation that requires an comparative analysis or clinical evaluation step to be carried out. When the claims are properly construed, Hanmi's theories of non-infringement of claims 1-11, 13-18 and 20-23 of the '192 patent fail. Consequently, the Court denies Hanmi's first motion for summary judgment.

C. Motion No. 5 - Non-Infringement of Unasserted Claims of the '504 Patent

Hanmi moves for summary judgment of non-infringement on claims 8 and 9 of the '504 patent.[1] These claims have not been asserted in this case by AstraZeneca. While AstraZeneca does not necessarily oppose Hanmi's motion as to these claim, *see* Pl. Br. at 1, its counsel has argued that Hanmi is seeking essentially an "advisory opinion" and has represented on the record that AstraZeneca will not assert claims 8 and 9 against Hanmi, Tr. 34:2-6.[2] The Court agrees that the motion is premature, and denies the motion without prejudice to Hanmi seeking judgment of non-infringement of these claims at an appropriate future time.

/s/ Joel A. Pisano
JOEL A. PISANO, U.S.D.J.

[1] Hanmi has also moved for summary judgment of non-infringement of claims 3, 5 and 10. However, AstraZeneca was granted leave to amend its Disclosure of Asserted Claims to add these claims after this motion was filed. Consequently, Hanmi's motion as to these claims is moot.

[2] "Tr." refers to the transcript of the oral argument held before the Court on June 20, 2012.